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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,667	10/29/2003	Mark L. Pomeranz	CRD5038	6834

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EXAMINER	
DOWE, KATHERINE MARIE	
ART UNIT	**PAPER NUMBER**
3734	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

NT

Office Action Summary	Application No.	Applicant(s)	
	10/696,667	POMERANZ ET AL.	
	Examiner	Art Unit	
	Katherine M. Dowe	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/29/2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/1/2006 and 5/23/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant is advised that should claim 30 be found allowable, claims 31 and 32 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 7, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaplan (US 5,342,348). Kaplan discloses a medical device (Fig 2A) comprising an expandable stent (2) which takes the form of a hollow tubular member comprised of an expandable wire frame (col 4, lines 48-51), having a small diameter (col 4, lines 51-56), a relatively thin wall, and a plurality of cells (Fig 2C, element 10) formed by a plurality of interconnected strut members (8 and 6) (col 11, lines 12-14). Kaplan discloses the device further comprises a plurality of elongated removable slat members (14 and 16) interwoven between a plurality of the strut members to temporarily attach the removable

slat to the tubular member and provide a cover for a portion of the peripheral surface of the tubular member (col 3, lines 36-39; col 6, lines 21-26; col 25, lines 25-33; col 11, lines 16-18).

4. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Hoganson et al. (US 2003/0074049). Hoganson et al. disclose a method of treating a bifurcated vessel with a stent covered with a polymer capable of releasing drugs or other therapeutic agents (pg 1, para 0002). The stent has an expandable tubular frame (Fig 19, element 10), a cover member (22) carried by the tubular frame, and including a detachable portion (220). The covered stent is inserted into a blood vessel and positioned adjacent a diseased portion of the vessel (Fig 29). The detachable portion is removed from the cover portion by withdrawing the detachable portion from the vessel therby allowing blood to flow through a portion of the cover member of the covered stent at the location of the detachable portion and into surrounding blood vessels (para 0125 and 0129-0131).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 3-6, 8-10, 12-15, 21-28, and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan (US 5,342,348), as applied to claim 2 above, in view of Rioux et al. (US 6,981,964). Kaplan discloses the invention substantially as claimed including removable slat members (14 and 16) interwoven through interconnected strut members (8 and 6) of an expandable stent (2). However, Kaplan does not disclose the removable slat members have tethers attached. Rioux et al. disclose a stent (Fig 16, element 50) with a portion (78) that may be removed by pulling a removal tether, or an elongated activation member, (80) selectively attached to that portion (col 16, lines 45-47). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the stent of Kaplan to include tethers, or an elongated activation members, attached to each removable slat acting as elongated puller wires such that the tethers could be selectively pulled to selectively remove the slats if the slats need to be removed during surgery. Furthermore, since Kaplan discloses the slat members (14 and 16) should be biodegradable such that they are removable when they are no longer useful, it would be obvious to make the added tethers biodegradable, and

thus removable, as well such that they will not have to be removed by an additional surgery when they are no longer useful.

8. Claims 16, 17, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan (US 5,342,348) in view of Masters et al. (US 2006/0167540) and Rioux et al. (US 6,981,964). Kaplan discloses the invention substantially as claimed including an expandable outer stent (2) which takes the form of a hollow tubular member comprised of an expandable wire frame (col 4, lines 48-51), having a small diameter (col 4, lines 51-56), a relatively thin wall, and a plurality of cells (Fig 2C, element 10) formed by a plurality of interconnected strut members (8 and 6) (col 11, lines 12-14). Kaplan discloses the device further comprises a plurality of elongated removable slat members (14 and 16) interwoven between a plurality of the strut members to temporarily attach the removable slat to the tubular member and provide a cover for a portion of the peripheral surface of the tubular member (col 3, lines 36-39; col 6, lines 21-26; col 25, lines 25-33; col 11, lines 16-18).

However, Kaplan does not disclose there is a second inner stent. Masters et al. disclose a medical device with an inner stent inserted into an outer stent (para 0001). Thus, an outer stent can have material that functions well with the vessel while the inner stent has material used to treat the vessel (para 0202), furthermore the outer stent may be smooth to interact harmlessly with the vessel, while the inner stent may aid in gripping a delivery catheter (para 0207). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of

Kaplan to include an inner stent similar to the outer stent provided. The inner stent should have a plurality of slats interwoven through it and be coaxially disposed within the outer stent, such that the slat members are aligned to obtain a substantially continuous cover for the medical device. Thus, more area is covered by the stent to apply the therapeutic agent from on the slat members more evenly about the vessel.

Furthermore, Kaplan does not disclose the removable slat members have tethers attached. Rioux et al. disclose a stent (Fig 16, element 50) with a portion (78) that may be removed by pulling a removal tether (80) selectively attached to that portion (col 16, lines 45-47). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the stent of Kaplan to include tethers, or elongated activation members, attached to each removable slat acting as elongated puller wires such that the tethers could be selectively pulled to selectively remove the slats if the slats need to be removed during surgery. Furthermore, since Kaplan discloses the slat members (14 and 16) should be biodegradable such that they are removable when they are no longer useful, it would be obvious to make the added tethers biodegradable, and thus removable, as well such that they will not have to be removed by an additional surgery when they are no longer useful.

9. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan (US 5,342,348) in view of Hoganson et al. (US 2003/0074049). Kaplan discloses the invention substantially as claimed including providing an expandable stent (Fig 2A, element 2), which takes the form of a hollow tubular member comprised of an

expandable wire frame (col 4, lines 48-51), having a small diameter (col 4, lines 51-56), a relatively thin wall, and a plurality of cells (Fig 2C, element 10) formed by a plurality of interconnected strut members (8 and 6) (col 11, lines 12-14). Kaplan discloses the device further comprises a plurality of elongated removable slat members (14 and 16) interwoven between a plurality of the strut members to temporarily attach the removable slat to the tubular member and provide a cover for a portion of the peripheral surface of the tubular member (col 3, lines 36-39; col 6, lines 21-26; col 25, lines 25-33; col 11, lines 16-18). Furthermore, Kaplan discloses the expandable stent is inserted into a blood vessel of a patient (col 9, lines 31-47).

However, Kaplan does not disclose the stent is used to treat aneurysms. Hoganson et al. disclose a method of treating aneurysms within a bifurcated vessel with a stent covered with a polymer capable of releasing drugs or other therapeutic agents (pg 1, para 0002). The stent has an expandable tubular frame (Fig 19, element 10), a cover member (22) carried by the tubular frame, and including a detachable portion (220). The covered stent is inserted into a blood vessel and positioning the stent such that is aligned with and covering an aneurysm in the blood vessel (Fig 29). The detachable portion is removed from the cover portion by withdrawing the detachable portion from the vessel thereby allowing blood to flow through a portion of the cover member of the covered stent at the location of the detachable portion and into surrounding blood vessels (para 0125 and 0129-0131). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify

the method of Kaplan such that the stent was used to treat aneurysms and such that the removable slats were selectively removed to provide flow to a branching blood vessel.

10. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan (US 5,342,348) in view of Hoganson et al. (US 2003/0074049), Masters et al. (US 2006/0167540), and Rioux et al. (US 6,981,964). Kaplan discloses the invention substantially as claimed including providing an expandable stent (Fig 2A, element 2), which takes the form of a hollow tubular member comprised of an expandable wire frame (col 4, lines 48-51), having a small diameter (col 4, lines 51-56), a relatively thin wall, and a plurality of cells (Fig 2C, element 10) formed by a plurality of interconnected strut members (8 and 6) (col 11, lines 12-14). Kaplan discloses the device further comprises a plurality of elongated removable slat members (14 and 16) interwoven between a plurality of the strut members to temporarily attach the removable slat to the tubular member and provide a cover for a portion of the peripheral surface of the tubular member (col 3, lines 36-39; col 6, lines 21-26; col 25, lines 25-33; col 11, lines 16-18). Furthermore, Kaplan discloses the expandable stent is inserted into a blood vessel of a patient (col 9, lines 31-47).

However, Kaplan does not disclose the stent is used to treat aneurysms. Hoganson et al. disclose a method of treating aneurysms within a bifurcated vessel with a stent covered with a polymer capable of releasing drugs or other therapeutic agents (pg 1, para 0002). The stent has an expandable tubular frame (Fig 19, element 10), a cover member (22) carried by the tubular frame, and including a detachable portion

(220). The covered stent is inserted into a blood vessel and positioning the stent such that is aligned with and covering an aneurysm in the blood vessel (Fig 29). The detachable portion is removed from the cover portion by withdrawing the detachable portion from the vessel thereby allowing blood to flow through a portion of the cover member of the covered stent at the location of the detachable portion and into surrounding blood vessels (para 0125 and 0129-0131). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Kaplan such that the stent was used to treat aneurysms and such that the removable slats were selectively removed to provide flow to a branching blood vessel.

Additionally, Kaplan does not disclose there is a second inner stent. Masters et al. disclose a medical device with an inner stent inserted into an outer stent (para 0001). Thus, an outer stent can have material that functions well with the vessel while the inner stent has material used to treat the vessel (para 0202), furthermore the outer stent may be smooth to interact harmlessly with the vessel, while the inner stent may aid in gripping a delivery catheter (para 0207). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Kaplan to include an inner stent similar to the outer stent provided. The inner stent should have a plurality of slats interwoven through it and be coaxially disposed within the outer stent, such that the slat members are aligned to obtain a substantially continuous cover for the medical device. Thus, more area is covered by the stent to apply the therapeutic agent from on the slat members more evenly about the vessel.

Furthermore, Kaplan does not disclose the removable slat members have tethers attached. Rioux et al. disclose a stent (Fig 16, element 50) with a portion (78) that may be removed by pulling a removal tether (80) selectively attached to that portion (col 16, lines 45-47). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the stent of Kaplan to include tethers attached to each removable slat acting as elongated puller wires such that the tethers could be selectively pulled to selectively remove the slats if the slats need to be removed during surgery. The tethers would allow the surgeon to easily pull the removable slats out of the stent and simplify the procedure.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6,042,605 – Martin et al.	US 2004/0186562 – Cox
US 6,030,414 – Taheri	2003/0139802 – Wulfman et al.
US 2003/0078647 – Vallana et al.	US 6,350,277 – Kocur

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine M. Dowe whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Hayes can be reached on (571)272-4959. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Dowe
December 19, 2006

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER